



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/553,007

08/07/2006

Claude Mialhe

0518-1161

1299

466 7590 03/30/2009

YOUNG & THOMPSON
209 Madison Street
Suite 500
ALEXANDRIA, VA 22314

EXAMINER

OU, JING RUI

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

03/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,007	Applicant(s) MIALHE, CLAUDE	
	Examiner JING OU	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the amendment filed along with an RCE on 01/28/2009. Claims 1-16 are pending. Claim 1 is independent.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/28/2009 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In paragraphs 5 and 6 of Claim 1, the recitations "an auto-expandable element (24) which presses against the internal wall of the outer envelope (2)" and "the auto-expandable element (24) is in contact with the

Art Unit: 3773

internal wall of the nose (14) does not have sufficient support in the original disclosure and are considered as new matters.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2-5, 11-13, 15, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the expandable element" in paragraph 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 11, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Vargas et al (US Pub. No. 2002/0042622).

In regard to Claims 1-5, 11, 15 and 16, Vargas et al discloses an implant delivery system, comprising: a vessel dilation device (deployment system 150 excluding anastomosis device 120 and the graft vessel 30, Fig. 5) with an outer envelope (outer trocar, 152, Fig. 5) and a tapered end piece (tapered end piece of 152, Fig. 5), whereby the end piece consists of a nose (the tapered end piece of 152 is a nose), means for opening the nose, consisting of at least two longitudinal slots which divide the nose into

Art Unit: 3773

several segments (Figures 5 and 6 and Para. [0062]); an implant (combination of anastomosis device 120 and graft vessel 30, Fig. 5), the implant includes an auto-expandable element (Para.[0111], nickel titanium alloy makes the element to be auto-expandable) which presses against the internal wall of the outer envelope (anastomosis device 120 and graft vessel 30 presses against the internal wall of the distal end of the outer envelope when 120 and 30 are pushed out of the 152, Fig. 7); means of translation of said implant in relation to the outer envelope such that the auto-expandable element is in contact with the internal wall of the nose in order to open out the segments (Fig. 7), the means of translation include an inner sheath (holder tube, 154, Fig. 5); the implant includes a second, hollow expandable element (shoulders 134, Fig. 5) and a hollow intermediate section (the intermediate section of 120 must be deformation by twisting, Fig. 5); a grip (distal fitting, 184, Fig. 5) that is an integral part of the outer envelope; a grip (medial fitting, 184, Fig. 5) that is an integral part of the inner sheath, and a plunger (expander tube, 156, Fig. 5).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 3773

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Garza et al (US Pat. No.: 4,665,918) in view of Martinez et al (US Pat. No.: 5,593,412).

In regard to Claims 1-16, Garza et al discloses an implant delivery system, comprising: a vessel dilation device (combination of prosthesis delivery catheter 18, sheath 50, and guiding catheter 78, Fig. 1) with an outer envelope (guiding catheter, 78, Fig. 1); an implant (prosthesis, 25, Fig. 5), the implant includes an auto-expandable element (distal portion of the prosthesis, Fig. 5) which presses against the internal wall of the outer envelope (Fig. 6, the prosthesis 25 presses against 50 and 78 when the prosthesis is enclosed in 78); means of translation, the means of translation include an inner sheath (sheath, 50, Fig. 5); the implant includes a second, hollow expandable element (the proximal end of the prosthesis 25, Fig. 5) and a hollow intermediate section (the intermediate section of the prosthesis 25 is deformable by twisting since it is an expandable stent, Fig. 5); a grip (hub, 86, Fig. 1) that is an integral part of the outer envelope; a grip (hub, 64, Fig. 1) that is an integral part of the inner sheath, a removable spacer (locking arms 72, Fig. 7, the combination of the locking arms 72 and 44 restrict the relative positions of hub 86 and hub 64 and a portion of locking arms 72 is situated between the hubs 86 and 64), a plunger (combination of proximal portion 22 and portion 24, Fig. 1), a grip (hub, 30, Fig. 1) that is an integral part of the plunger, a second removable spacer (hubs, 44, Fig. 7), means (the separated portions 58 is

Art Unit: 3773

capable of rotating the inner sheath and thus adjusting the angle of the inner sheath) of adjusting the angle of the inner sheath, and a central channel (the channel of guiding catheter, Fig. 1) along the line of the outer envelope.

Garza et al does not appear to disclose that the outer envelope has a tapered end piece and detailed structures of the end piece.

However, Martinez et al explicitly discloses an implant delivery system, comprising of an outer envelope (sheath, 18, Fig. 1) having a tapered end piece (distal end portion 32 is tapered, Fig. 1) at the distal end of the outer envelope and an implant have expandable portion (stent, Fig. 10) that is pressed against the sheath and is in contact with the internal wall of a nose, whereby the end piece consists of the nose (the tapered distal end portion 32 is nose, Fig. 1) and means for opening the nose, consisting of at least two longitudinal slots (weakened areas, 41-45, Fig. 2A) which divide the nose into several segments (sections, 51-55, Fig. 2A), nose segments are joined as required along the slots when the nose is closed (Fig. 2A, the nose segments are joint by connector as shown in Fig. 2A); temporary connector by slots between segments (Fig. 2A, the nose segments are joint by connector as shown in Fig. 2A); and the nose includes a central residual passage (central opening, 50, Fig. 2A).

Garza et al and Martinez et al are analogous art because they are from the same field of endeavor, implant delivery system.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Garza et al and Martinez et al before him or her, to

Art Unit: 3773

modify the implant delivery system of Garza et al to include an outer envelope having a tapered end piece and detailed structures of the end piece as taught by Martinez et al.

The suggestion/motivation for doing so would have been to protect the implant from premature deployment and control the deployment of the implant. Until the delivery device reaches a target site, the distal end portion of the sheath is softened by exposing to a warm, physiologically compatible liquid and opened by the pushing force of the implant and the introducer, thereby to allow for retraction of the sheath and deployment of the implant (Martinez et al, Col. 3, lines 24-42). Applicant should have noted that the tapered end piece is old and well-known in the art. Furthermore, it is old and well-known that the nose include a shape memory, which would facilitate the withdrawn of the delivery system from body or enable insertion of another implant without withdrawing the sheath out of the body.

Therefore, it would have been obvious to combine Martinez et al with Garza et al to obtain the invention as specified in the instant claims.

Response to Arguments

12. Applicant's arguments filed 01/18/2009 have been fully considered but they are not persuasive. The allegation on page 9 and 10 of the remarks that the anastomosis device 120 is not expanded to press against the internal wall of the trocar 152 is incorrect. As shown in Figure 7, the combination of 120 and 30 is expanded to press against the internal wall of the trocar 152. The implant is now defined as the combination of 120 and 30.

The allegation on page 12 of the remarks that the combined references does not teach "an implant with an auto-expandable element which presses against the internal wall of an outer envelope, and a mean for translation of said implant in relation to the outer envelope such that the auto-expandable element is in contact with the internal wall of the nose of the outer sleeve to open out the outer sleeve segments" is incorrect. Garza et al clearly discloses an implant (prosthesis, 25, Fig. 5) including an auto-expandable element (distal portion of the prosthesis, Fig. 5) which presses against the internal wall of the outer envelope (Fig. 6, the prosthesis 25 presses against 50 and 78 when the prosthesis is enclosed in 78). In addition, Martinez et al explicitly teaches an implant delivery system, comprising of an outer envelope (sheath, 18, Fig. 1) having a tapered end piece (distal end portion 32 is tapered, Fig. 1) at the distal end of the outer envelope and an implant have expandable portion (stent, Fig. 10) that is pressed against the sheath and is in contact with the internal wall of a nose, whereby the end piece consists of the nose (the tapered distal end portion 32 is nose, Fig. 1). The suggestion/motivation for doing so would have been to protect the implant from premature deployment and control the deployment of the implant. Until the delivery device reaches a target site, the distal end portion of the sheath is softened by exposing to a warm, physiologically compatible liquid and opened by the pushing force of the implant and the introducer, thereby to allow for retraction of the sheath and deployment of the implant (Martinez et al, Col. 3, lines 24-42).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773

Application/Control Number: 10/553,007
Art Unit: 3773

Page 10